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February 3, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/615158
For: *EPA AND DHA ENRICHED OMEGA-3 SUPPLEMENT FOR THE
TREATMENT OF DRYE EYE MEIDOMIANITIS AND XEROSTIMIA*
Inventor: Gilbard, Jeffrey P.
Filed: July 7, 2003
Our Ref. No.: AVR-005

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB/08;
3. Copies of publications cited in PTO Form SB/08 (8); and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

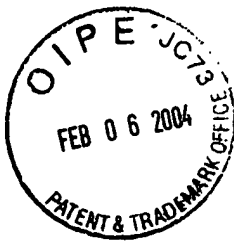
February 3, 2004

Date

Ralph A. Loren, Reg. No. 29,325

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Ralph A. Loren
Registration No. 29,325
Attorney for Applicant



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Gilbard, Jeffrey P.

Serial No.: 10/615158

Filed: July 7, 2003

For: *EPA AND DHA ENRICHED OMEGA-3
SUPPLEMENT FOR THE TREATMENT OF DRY
EYE MEIDOMIANITIS AND XEROSTOMIA*

Attorney Docket No.: AVR-005

Group Art Unit: 1614

Examiner: Not Yet Assigned

Commissioner for Patents
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February 3, 2004

Date of Signature and of Mail Deposit

By: 

Ralph A. Loren
Registration No. 29,325
Attorney for Applicant

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicant and his Attorney are aware of the following publications and information, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicant understands that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR   1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR  1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

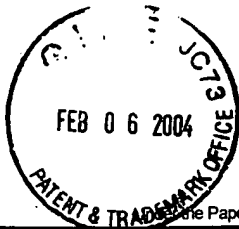


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Date: February 3, 2004

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Enclosures



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| | | | | Application Number | 10/615158 |
| | | | | Filing Date | July 7, 2003 |
| | | | | First Named Inventor | Gilbard, Jeffrey P. |
| | | | | Art Unit | 1614 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | AVR-005 |

| U.S. PATENT DOCUMENTS | | | | | |
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| | A1 | Akbar, M. <i>et al.</i> "Protective effects of docosahexaenoic acid in staurosporine-induced apoptosis: involvement of phosphatidylinositol-3 kinase pathway." <i>Journal of Neurochemistry</i> 82:655-665 (2002). | | | |
| | A2 | Caughey, G.E. <i>et al.</i> "The effect on human tumor necrosis factor α and interleukin 1β production of diets enriched in n-3 fatty acids from vegetable oil or fish oil." <i>Am. J. Clin. Nutr.</i> 63:116-22 (1996). | | | |
| | A3 | Curtis, C.L. <i>et al.</i> "n-3 fatty acids specifically modulate catabolic factors involved in articular cartilage degradation." <i>The Journal of Biological Chemistry</i> 275(2):721-724 (2000). | | | |
| | A4 | Kishida, E. <i>et al.</i> "Distinctive inhibitory activity of docosahexaenoic acid against sphingosine-induced apoptosis." <i>Biochimica et Biophysica Acta</i> 1391:401-408 (1998). | | | |
| | A5 | Kronemyer, B. "Dry eye successfully treated with oral flaxseed oil." <i>Ocular Surgery News EUROPE/ASIA-PACIFIC EDITION</i> retrieved from the internet at http://www.osnsupersite.com/default.asp?ID=390 2pp. (2000). | | | |
| | A6 | Oxholm, P. <i>et al.</i> "Essential fatty acid status in cell membranes and plasma of patients with primary Sjögren's syndrome." <i>Prostaglandins, Lukotrienes and Essential Fatty Acids</i> 59(4):239-245 (1998). | | | |
| | A7 | Sullivan, B.D. <i>et al.</i> "Correlations between nutrient intake and the polar lipid profiles of meibomian gland secretions in women with Sjögren's syndrome." in <u>Lacrimal Gland, Tear Film, and Dry Eye Syndromes 3</u> edited by Sullivan, D. <i>et al.</i> , Kluwer Academic/Plenum Publishers pp.441-447 (2002). | | | |
| | A8 | Yano, M. <i>et al.</i> "Docosahexaenoic acid and vitamin E can reduce human monocytic U937 cell apoptosis induced by tumor necrosis factor." <i>J. Nutr.</i> 130(5):1095-1101 (2000). | | | |

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